

**Remarks**

This amendment is responsive to the Office Action of September 28<sup>th</sup> 2004. Reconsideration of amended claims 1-12, 14-18, 23, 25, 27-28, 30-32, 35-39, and 42-43 and the new claims 44-53 are respectfully requested.

**The Office Action**

Claims 21-41 are withdrawn under 35 U.S.C. § 121 and 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 1, 14, 16-19, and 42-43 stand rejected under 35 U.S.C. § 102 (b) as being anticipated by ANTRIM et al. U.S. Patent Number 4,963,385.

Claims 4-5, and 15 stand rejected under 35 U.S.C. § 102 (b) or in the alternative under 35 U.S.C. § 103 (a) as being anticipated by ANTRIM et al. U.S. Patent Number 4,963,385 optionally in view of BUIKSTA et al. U.S. Patent Number 5,650,190.

Claims 6-12 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over ANTRIM et al. U.S. Patent Number 4,963,385 in view of MUSHER et al. U.S. Patent Number 2,282,815.

Claims 2-3 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over ANTRIM et al. U.S. Patent Number 4,963,385 in view of DEMICHELE et al. U.S. Patent Number 5,223,285 or KAHN et al. U.S. Patent Number 4,421,778.

Claim 13 stands rejected under 35 U.S.C. § 103 (a) as being unpatentable over ANTRIM et al. U.S. Patent Number 4,963,385 in view of CANTE et al. U.S. Patent Number 3,887,715.

Claim 20 stands rejected under 35 U.S.C. § 103 (a) as being unpatentable over ANTRIM et al. U.S. Patent Number 4,963,385 in view of KIERULFF et al. U.S. Patent Number 6,298,859 or LINDSAY et al. U.S. Patent Number 4,915,876 or SCHROEDER et al. U.S. Patent Number 5,116,629.

Claims 1-3, 6-7, 9, 16 and 42-43 stand rejected under 35 U.S.C. § 102 (b) as being anticipated by KAHN et al. U.S. Patent Number 4,421,778.

### 35 U.S.C. § 112

The applicant has carefully amended the claims to address each of the points raised by the Examiner. It is submitted that all claims now comply fully with the requirements of 35 U.S.C. § 112. Applicant considers that the claims are supported by the application as originally filed and are novel as compared to references of record.

### The References of Record

ANTRIM et al. U.S. Patent Number 4,963,385 is directed to a oxidative stabilized emulsion for highly unsaturated oils which is comprised of sugars and/or sugar alcohols and a metal-ion chelator. In such a composition, there is no distinction between reducing and non-reducing sugars. There is no suggestion of using non-reducing sugars preferentially over reducing sugars. Furthermore, there is no distinction between natural and synthetic metal-ion chelators. There is no suggestion that any metal-ion chelator or that multiple metal-ion chelators achieve superior results. Addition of metal-ion chelators without the presence of commercial antioxidants cannot lengthen shelf-life of unsaturated oils, in particular highly unsaturated oils.

BUIKSTA et al. U.S. Patent Number 5,650,190 is directed to an emulsifying agent that stabilizes the emulsion subjected to heat. In such a composition, the objective is to prevent emulsions that destabilize spontaneously (separation of oil and water phases). There is no mention or implication that stability incorporates oxidative stability as further attributed to the complete absence of terms oxidation, antioxidant, or free radical, and any known antioxidants. Thus the inclusion of emulsifying agents within BUIKSTA et al. does not anticipate such emulsifying agents as contributing to oxidative stability, nor contributing to enhanced stability during prolonged shelf life under room temperature conditions (i.e., non-heated).

MUSHER et al. U.S. Patent Number 2,282,815 is directed to stabilization of oils during the refining process, which has very high temperature requirements as compared to shelf-life

stability. In such a composition, the enhanced antioxygenic effect is only obtained at processing temperatures in excess of 250 °F. The heating process is in fact required to achieve dispersion of the stabilizing agents noted as phosphatides, phosphoric acid and the salts of phosphoric acid and a nitrogen compound. There is no suggestion that elimination of the heating process will enhance the antioxygenic effect, which by inference is required to disperse the stabilizing agents, whereas our invention MORA-GUTIERREZ et al. requires mixing of different stabilizing agents at room temperature and within an emulsion both notably absent from MUSHER et al. Furthermore, in such a composition, there is also no distinction between reducing and non-reducing sugars. There is no suggestion of using non-reducing sugars preferentially over reducing sugars.

DEMichele et al. U.S. Patent Number 5,223,285 is directed to a nutritional product for pulmonary patients, which has antioxidant properties in vivo. In such a composition an emulsion is made which itself requires emulsifying and emulsion stabilizing agents thus the inclusion of soy lecithin and carrageenan. Medium chain triglycerides “MCT” is also recognized nutritional properties as being digested preferably within the proximal intestine and differently than traditional fats and oils. The composition being a nutritional product further requires proteins for recognized nutritional properties with specific note of intact milk (i.e., acid casein slurry) and soy proteins for the precise purpose of both being high quality proteins with high biological values. There is no suggestion that the acid casein is used for anything except for nutritional properties and to adjust pH to the specification of 6.4 to 7.1, which is notably above the desired pH in our invention of MORA-GUTIERREZ et al. of pH 2.0 to 5.7 and more preferably less than 4.5. There is no suggestion of using casein, carrageenans, or lecithin as promoters of oxidative stability beyond the beta-carotene, vitamin E, vitamin C, selenium or taurine. Furthermore, no reference to product shelf life or any of the associated parameters associated with shelf life exist (e.g., temperature, metal ions, etc.).

KAHN et al. U.S. Patent Number 4,421,778 is directed to freezer stable ice cream and milk products, which explicitly maintains stable volume. In such a composition, the objective is to prevent whipped (i.e., high volume) emulsions that destabilize at prolonged refrigerated and freezer temperatures (reduction of whipping and spoonability). There is no mention or implication that stability incorporates oxidative stability as further attributed to the complete

absence of terms oxidation, antioxidant, or free radical, and any known antioxidants. Thus the inclusion of emulsifying agents, casein containing sources, non-reducing sugars, calcium carrageenan, medium chain triglycerides, and other such food ingredients including cocoa, soybean oil, and coconut oil within KAHN et al. does not anticipate such ingredients as contributing to oxidative stability, nor contributing to enhanced stability during prolonged shelf life under any temperature conditions (including heated or room temperatures). Lastly, the inclusion of medium chain triglycerides within KAHN et al. is specifically noted as an emulsifier and not as a means of delivering minerals preferentially to the proximal intestine.

CANTE et al. U.S. Patent Number 3,887,715 is directed to a stable emulsion comprised of a proteose peptone (i.e., “protein-aceous” emulsifier) precipitated from the whey fraction. In such a composition, the objective is to limit the protein-aceous emulsifiers selected from the class of whey proteins, wherein casein is non-desirable in CANTE et al. as specifically noted that “casein is insoluble in safflower oil (i.e., high in unsaturated fats / oils) and does not reduce the oil/air interfacial tension. Hence in terms of surface activity at the oil/water interface proteose peptone can be expected to be more active than casein”. Thus, the inclusion of casein proteins is not anticipated. Furthermore, there is no suggestion that the protein-aceous emulsifiers in general, or more specifically the proteose peptone is either digested, or enzymatically modified in any manner (e.g., enzymatic hydrolysis). Lastly, there is no suggestion that proteose peptone is complexed, or preferably complexed with calcium or magnesium to form a complex with enhanced solubility.

KIERULFF et al. U.S. Patent Number 6,298,859 is directed to a phenol oxidizing enzyme in tobacco. In such a composition, the objective is specifically to destroy the impact of polyphenols in tobacco, which is completely opposite of the desire within MORA-GUTIERREZ et al. to enhance the impact of polyphenols. There is no suggestion that a phenol oxidizing enzyme would provide any antioxidant benefits, regardless of the source being from *Solanum melongena*, when in fact the enzyme is a pro-oxidant. Lastly, CANTE et al. provides no further suggestion in view of KIERULFF et al.

LINDSAY et al. U.S. Patent Number 4,915,876 is directed to the deodorization and stabilization of polyunsaturated oils. In such a process, the objective is to remove unsaturated carbonyls with acid treatment. There is no suggestion that any of the acidifying additives remain

within the polyunsaturated oils following the acidifying process, nor any suggestion that in fact the acids, including citric acid, themselves have any antioxidant benefits. Furthermore, there is no suggestion that phospholipids remain within the deodorized oils following the acidifying process, nor that the phospholipids themselves have any antioxidant benefits. In fact there is direct mention of the requirement “to add as much conventional antioxidant as is legally permissible to provide their stability benefits to the oil upon extended storage” to substantiate the fact that LINDSAY et al did not anticipate any inherent antioxidant benefits except with the addition of such conventional antioxidants. Lastly, CANTE et al. provides no further suggestion in view of LINDSAY et al.

SCHROEDER et al. U.S. Patent Number 5,116,629 is directed to processed meat products containing fish oils stabilized by fructose. In such a composition the objective is to stabilize a non-fish protein from rancidity with the inclusion of fructose and “a fish oil stabilizing antioxidant”. There is no suggestion that fructose itself is an antioxidant as dictated by the independent claim that specifically requires the inclusion of “a fish oil stabilizing antioxidant”. Therefore it is not anticipated that fructose is an antioxidant, but rather an antioxidant enhancer. Furthermore, the noted “fish oil stabilizing antioxidant”(s) are known within the art of artificial / synthetic antioxidants. Lastly, SCHROEDER et al. specifically exclude the inclusion of a foreign protein, fish protein as noted in the composition, further substantiating the lack of anticipating the inclusion of a foreign protein or modified protein as being advantageous to the reduction of oxidation. SCHROEDER et al. also specifically note the inclusion of lecithin (i.e., phospholipids) as being detrimental to the shelf life of processed meat products. Lastly, CANTE et al. provides no further suggestion in view of SCHROEDER et al.

CHANG et al. U.S. Patent Number 5,077,069 is directed to natural antioxidants to stabilize polyunsaturated oils. The composition of acids, tocopherols, and phospholipids, which doesn’t introduce any new art as compared to LINDSAY et al., is really a process to disperse non-oil soluble components within an oil. The process includes the use of non-desirable solvents (e.g., hexane and anhydrous ethanol) to disperse the non-oil soluble components. There is no suggestion that the invention is relevant to either an oil/water or water/oil emulsion. In fact the requirement for the noted solvents and thus the only novel component to the invention of using a solvent to disperse the noted additives is eliminated. Lastly, CANTE et al. provides no further suggestion in view of CHANG et al.

**The Claims Distinguish Patentably Over the References of Record**

None of the references of record suggest the use of proteins from the casein fraction of milk or any modification of such proteins as an antioxidant, as a means to prevent bone mineral loss, or as a means to prevent hypercholesterolemia.

ANTRIM et al. U.S. Patent Number 4,963,385 fails to disclose any distinction between reducing and non-reducing sugars and sugar polyols. Furthermore, in the invention of MORA-GUTIERREZ et al., chitosan (i.e., is not a metal chelator) assumes a polycationic character at acidic pH (pH 2.0-5.7). This polycationic chitosan molecule reacts with the high negative charge contributed by the phosphate groups of caprine casein phosphopeptide to form a “polycationic complex”. This polycationic complex reacts with the phosphate groups of lecithin-emulsified oil droplets and sulfated groups of polysaccharides (carrageenans, heparin, chondroitin, dextran, and cyclodextrins) to form a BIOPOLYMERIC COMPLEX. This biopolymeric complex efficiently ENCAPSULATES “natural” antioxidants such as the VITAMIN E complex (tocotrienols, tocopherols) and pro-VITAMIN A (beta-carotene). The polyphenols present in the eggplant fruit (*Solanum melongena*) can be used in combination with the BIOPOLYMERIC COMPLEX to effectively inhibit peroxide formation in emulsified lipids.

BUIKSTA et al. U.S. Patent Number 5,650,190 fails to disclose or suggest any benefits from the emulsifying agents beyond recognized emulsification.

MUSHER et al. U.S. Patent Number 2,282,815 fails to provide an inherent method to disperse stabilizing agents without temperatures in excess of 250 °F. It further fails to disclose any distinction between reducing and non-reducing sugars and sugar polyol.

DEMICHÈLE et al. U.S. Patent Number 5,223,285 fails to disclose or suggest that any oxidative stability during oil processing or shelf life storage is achieved. It further fails to suggest any purpose of the acid casein slurry beyond pH adjustment and a protein source.

KAHN et al. U.S. Patent Number 4,421,778 fails to disclose or suggest that the inclusion of emulsifying agents, casein containing sources, non-reducing sugars, calcium carrageenan, medium chain triglycerides, or other such food ingredients including cocoa, soybean oil, and

coconut oil contributes to the oxidative stability, or enhanced stability during prolonged shelf life under any temperature conditions (including heated or room temperatures).

CANTE et al. U.S. Patent Number 3,887,715 fails to disclose or suggest the use of proteins from the casein fraction of milk or any modification of such proteins as an antioxidant. Please further note CANTE et al. refers to the use of “proteose peptone proteins from cow’s (bovine) milk” to stabilize aqueous-unsaturated oil emulsions as the emulsifier. If you take close a look at the method of preparation (see Page 2; Paragraph 5), the bovine milk is acidified to pH 4.7. Although it is not stated, 1 N HCl is the acid of choice to bring done pH of milk. Whereas, MORA-GUTIERREZ et al. use chitosan solubilized in 10% (w/v) citric acid to bring done the pH of caprine milk to pH 4.7. We also used 50% ethanol to precipitate 100% casein phosphopeptides (zero traces of whey proteins). The proteose-peptone proteins of CANTE et al. are precipitated with 12% (w/v) trichloroacetic acid and are enriched with whey proteins: albumin, immunoglobulins, alpha-lactalbumin, beta-lactoglobulin) and glycoproteins both of which exhibit significant “surface activity”. In CANTE et al., the proteose peptone fraction is used as a “proteinaceous emulsifier” and is precipitated from cow’s milk (not the whey fraction). The whey protein and the proteose peptone fractions are the only milk proteins responsible for the enhanced emulsifying properties exhibited in aqueous-unsaturated oil emulsions.

KIERULFF et al. U.S. Patent Number 6,298,859 fails to disclose or suggest that a phenol oxidizing enzyme would provide any antioxidant benefits, regardless of the source being from *Solanum melongena*, when in fact the enzyme is a pro-oxidant.

LINDSAY et al. U.S. Patent Number 4,915,876 fails to disclose any permanent inclusion of ingredients within a final product containing such stabilized oils except as a processing step.

SCHROEDER et al. U.S. Patent Number 5,116,629 fails to disclose any antioxidant benefits except when fructose is combined with known fish oil stabilizing antioxidants.

CHANG et al. U.S. Patent Number 5,077,069 fails to disclose any benefits within an emulsion, and yet further requires an anhydrous blend of oil and additives.

## CONCLUSION

For the reasons set forth above, it is submitted that modified claims 1-12, 14-18, 23, 25, 27-28, 30-32, 35-39, and 42-43 and the new claims 44-53 distinguish patentably and unobviously over the references of record. An early allowance of these claims is earnestly solicited.

Respectfully submitted,

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## CERTIFICATE OF MAILING

I hereby certify that this **AMENDMENT** in connection with U.S. Patent Application Serial No. 10/784,842 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

Date: November 30<sup>th</sup> 2004 by Michael Gurin {Michael Gurin}